

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION**

NATIONAL INFUSION CENTER)	
ASSOCIATION, et al.,)	
Plaintiffs,)	
)	
v.)	No. 1:23-cv-00707-DAE
)	
ROBERT F. KENNEDY, JR., in his official)	
Capacity as Secretary of the U.S. Department of)	
Health and Human Services, et al.)	
Defendants.)	
)	

**MOTION OF PUBLIC CITIZEN, DOCTORS FOR AMERICA, PROTECT OUR CARE,
AND FAMILIES USA FOR LEAVE TO FILE BRIEF OF AMICI CURIAE**

Public Citizen, Doctors for America, Protect Our Care, and Families USA respectfully move for leave to file a memorandum as amici curiae in support of the Defendants' Cross-Motion for Summary Judgment and Opposition to Plaintiffs' Motion for Summary Judgment. All parties consent to the filing of this amicus brief.

BACKGROUND

Enacted in August 2022, the Inflation Reduction Act (IRA) contains several reforms designed to lower the high cost of prescription drugs and make them more accessible to patients, including seniors enrolled in Medicare. *See* Pub. L. No. 117-169, § 11001-11003 (codified at 42 U.S.C. §§ 1320f–1320f-7 and 26 U.S.C. § 5000D). One such reform is the IRA's drug price negotiation program, which provides a pathway to lower the prices for a particular set of high-cost drugs—so-called single-source drugs, for which no generic equivalent is currently on the market. The program relies on a process in which the Department of Health and Human Services (HHS),

which is responsible for implementing Medicare, and the manufacturer of selected drugs negotiate the prices at which drugs will be made available to Medicare providers and drug plans.

Plaintiffs National Infusion Center Association, the Global Colon Cancer Association, and Pharmaceutical Research and Manufacturers of America sued Defendants, alleging a Due Process claim among other claims. Plaintiffs moved for summary judgment on January 10, 2025. ECF No. 60. Defendants opposed Plaintiffs' motion and cross-moved for summary judgment on April 21, 2025. ECF No. 70.

INTERESTS OF MOVANTS

Movants are four non-profit organizations with expertise in public health and with longstanding interests in patients' access to health care, including affordable medicines. Movants share an interest in the promotion and implementation of policies that make access to medications more accessible to the patients who need them, thereby improving health outcomes, saving lives, and protecting the financial health of individuals and families. Movants believe that the Inflation Reduction Act's drug price negotiation program is an important step toward reining in the high cost of prescription drugs for patients enrolled in Medicare, and they are concerned that Plaintiffs' arguments, if accepted by this Court, would result in substantial harm to the health and finances of seniors and other Medicare patients.

Public Citizen is a nonprofit consumer advocacy organization with members and supporters in all 50 states. Public Citizen advocates before Congress, administrative agencies, and courts on a wide range of issues, including issues concerning consumer health and safety. A central concern of Public Citizen is protecting and expanding access to affordable medicines for consumers, both domestically and globally. To advance that interest, Public Citizen works with partners worldwide to improve health outcomes and save lives by advancing policies to lower

pharmaceutical prices. Public Citizen has provided technical assistance concerning patent rules and access to medicines to dozens of governments and international organizations.

Doctors for America mobilizes doctors and medical students to be leaders in putting patients over politics on the pressing issues of the day to improve the health of their patients, communities, and nation. A non-partisan, nonprofit, non-trade organization working on patients' behalf, Doctors for America is continuously working to improve access to equitable, affordable, high-quality health care for patients across the country. For this reason, Doctors for America has a longstanding history of working to improve drug affordability by advocating for legislative, regulatory, and judicial changes to ensure that patients can access life-sustaining treatments.

Protect Our Care, a fiscally sponsored project of the New Venture Fund, is dedicated to making high-quality, affordable, and equitable health care a right, and not a privilege, for everyone in America. Protect Our Care educates the public, influences policy, supports health care champions, and holds lawmakers accountable. Protect Our Care supported the development and enactment of the Inflation Reduction Act's provisions to make prescription drugs more affordable, including the Medicare drug price negotiation program. Protect Our Care is committed to the successful implementation of the Act to ensure that seniors and taxpayers benefit from more affordable prescription drugs.

Families USA is a non-partisan voice for health care consumers and is dedicated to achieving high-quality, affordable health care and improved health for all. On behalf of health care consumers, working people, and patients, Families USA has advocated for decades for legislation and rulemaking that improves the accessibility and affordability of prescription drugs. Families USA believes that ensuring drug affordability should be a key part of the Medicare Part D program and has urged policymakers to explore the root causes of high and irrational drug prices and to

tackle the complex network of abusive practices that underpin the American pharmaceutical market.

ARGUMENT

The decision whether to permit amici curiae rests within the “broad discretion” of the district court. *Evanston Ins. Co. v. Rodriguez Eng’g Lab’ys*, 2023 WL 379277, at *1 (W.D. Tex. Jan. 20, 2023) (citation omitted); *see also Pacheco v. Freedom Buick GMC Truck, Inc.*, 2011 WL 13234884, at *1 (W.D. Tex. Nov. 1, 2011) (recognizing “the district court’s inherent authority to allow the participation of amicus under conditions that the court finds appropriate”). “Generally, the function of an amicus brief is to aid the court with matters apparent on the record or matters of practice that may otherwise escape the Court’s consideration.” *United States v. Holy Land Found. For Relief & Dev.*, 2009 WL 10680203, at *2 (N.D. Tex. July 1, 2009), *rev’d on other grounds*, 624 F.3d 685 (5th Cir. 2010) “An amicus brief is proper when it assists the judge by presenting aspects of ideas, arguments, theories, facts or data that are not in the parties’ briefs.” *Id.* In addition, the Court has “discretion to consider ‘amicus’ briefing where ‘the proffered information is ‘timely and useful’ or otherwise necessary to the administration of justice.’” *Does 1-7 v. Round Rock Indep. Sch. Dist.*, 540 F. Supp. 2d 735, 739 n.2 (W.D. Tex. 2007); *see Evanston Ins. Co.*, 2023 WL 379277, at *1 (similar).

Here, the information and arguments set out in the proposed amicus brief by organizations focused on the public interest and with expertise on this topic will be useful to this Court in resolving the pending summary judgment motions. The proposed memorandum explains that Congress’s prior efforts to improve Medicare enrollees’ access to provider-administered medications and prescription drugs have not been sufficient to prevent significant increases in the drug prices that have left many enrollees unable to afford their out-of-pocket payments. As the

proposed amicus memorandum explains, many Medicare enrollees consequently forgo medications that they cannot afford or sacrifice other essential needs in order to pay for their medications. The IRA price-negotiation program addresses affordability by providing a means for negotiating lower drug prices and thereby improving seniors' access to Medicare-covered drugs.

In addition, the proposed amicus brief explains that a core premise of Plaintiffs' due process challenge is wrong. Plaintiffs' due process claim is based on the notion that the IRA program imposes "price controls" that "replace[s] the 'free market' system ... for drug pricing" and that the "market-based" price of a drug is whatever price drug companies would otherwise charge Medicare participants absent negotiation. Pls. Mem. 1. Anything below that amount, Plaintiffs suggest, deprives providers, manufacturers, and patients of their property interests. *See* Pls. Mem. 24–27. As the proposed amicus memorandum explains, however, Plaintiffs' theory is built on a faulty premise: that the price a monopolist charges for its product is necessarily the "market price[]" for the drug and that Plaintiffs and their members have a property interest in maintaining that price. *Id.* at 26. That premise is wrong. And absent any showing that the drug prices negotiated under the IRA program necessarily deprive Plaintiffs and their members of property interests, Plaintiffs' due process challenge must be rejected.

The proposed amicus memorandum is timely because it will not delay the briefing or argument in this case, and Plaintiffs will have the opportunity in its reply to respond to the arguments in the proposed memorandum. The proposed amicus memorandum is attached to this motion.

CONCLUSION

The Court should grant this motion for leave to file an amicus curiae memorandum.

April 22, 2025

Respectfully submitted,

/s/ Aaron Johnson _____

Aaron Johnson
TX Bar No. 24056961
ajohnson@fairlaborlaw.com
Fair Labor Law PLLC
314 E. Highland Mall Blvd., Ste. 401
Austin, TX 78752
Ph: (512) 277-3505
Fax: (512) 277-3254

Nandan M. Joshi (*pro hac vice* motion pending)
D.C. Bar No. 456750
njoshi@citizen.org
Public Citizen Litigation Group
1600 20th Street NW
Washington, DC 20009
Ph: (202) 588-1000

Attorneys for Movants Public Citizen, et al.